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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/367,714	01/14/2000	YECHIEL SHAI	SHAI=2	4669

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BROWDY AND NEIMARK, P.L.L.C.  
624 NINTH STREET, NW  
SUITE 300  
WASHINGTON, DC 20001-5303

EXAMINER

LUKTON, DAVID

ART UNIT PAPER NUMBER

1653

DATE MAILED: 04/03/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/367,714

Applicant(s)

SHAI ET AL.

Examiner

David Lukton

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 December 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-14, 20, 21, 27-35 and 37 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 34, 35 and 37 is/are allowed.
- 6) ☒ Claim(s) 1 and 7-11 is/are rejected.
- 7) ☒ Claim(s) 2-6, 12-14, 20, 21 and 27-33 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

Pursuant to the directives of paper No. 24 (filed 12/17/02), claims 1, 14, 31, 32 have been amended. Claims 1-14, 20, 21, 27-35, 37 remain pending. Applicants' arguments filed 12/17/02 have been considered and found persuasive in part. The rejection of claims 1, 2, 7-11, 20 over Maloy ('831) is withdrawn.

Claims 2-6, 12-14, 20, 21, 27-33 are objected to because of their dependence on rejected claims. Claims 34, 35 and 37 are characterized as allowable.

※

The following is a quotation of the appropriate paragraphs of 35 U.S.C §102 that form the basis for the rejections under this section made in this action.

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 7 are rejected under 35 U.S.C. §102(b) as being anticipated by Shai (*J. Biol. Chem.* **271**, 7305, 1996).

Shai discloses (page 7306, table I) the peptides designated "(D)P<sup>7</sup>" and (D)L<sup>18</sup>L<sup>19</sup>. Also disclosed (page 7307) is that "(D)P<sup>7</sup>" is cytolytic (against *bacillus megaterium*) at a concentration of 1.2 μM, while at the same time is not hemolytic at this concentration. Similarly, Shai discloses (e.g., page 7307) that (D)L<sup>18</sup>L<sup>19</sup> is cytolytic (against *bacillus megaterium*) at a concentration of 0.6 μM, while at the same time is not hemolytic at this

concentration. The claims permit the peptide to be both hemolytic and cytolytic, as long as the concentration required for hemolysis is higher than that required for cytotoxicity.

Thus, the claims are anticipated.

In the response filed 12/17/02, it is argued that a §102 rejection based on Shai would be improper predicated on an assumption that claim 1 encompasses the peptide designated "(D)P<sup>7</sup>L<sup>18</sup>L<sup>19</sup>". This specific peptide has been excluded from claim 1; however, Shai additionally discloses peptides designated "(D)P<sup>7</sup>" and "(D)L<sup>18</sup>L<sup>19</sup>" which still anticipate the claims.

\*

Claims 1 and 7 are rejected under 35 U.S.C. §102(b) as being anticipated by Lakey, Jeremy (*Biochim Biophys Acta* **859**, 219-226, 1986).

Lakey discloses analogs of the lipopeptide antibiotic A21978C. The analogs differ from A21978C in the length and branching of the acyl group bonded to the N-terminus of tryptophan (see, e.g., fig. 1). Also disclosed (e.g., page 224, col 2, paragraph 2) is that A21978C is cytotoxic at much lower concentrations than it is hemolytic.

Claim 1, part (B) conveys that if each D-amino acid that is present in the peptide is replaced with its enantiomer, the result must be a peptide in which the "amino acid sequence" is not found in nature. Where the amino acids are limited to those that are naturally occurring, and there are no other modifications that are stated or implied, it is clear

what is meant by the term "amino acid sequence". In the instance where all naturally occurring "amino acid sequences" are excluded, the "amino acids" are not confined to those that are genetically encoded, or even those that are produced by prokaryotes. Specifically, tryptophan does not lose its property of being an "amino acid" if it is acylated. The claims do not state or imply that the only way that an amino acid can differ from one found in nature is by modification of a side chain. The peptides to which the claims are drawn are not confined to *alpha*- amino acids; thus *beta*-, *gamma*-, *delta*-, *epsilon*- (etc.) amino acids are included. With respect to the Lakey reference, the N-acyltryptophan is an amino acid which is not found in nature (at least those N-acyl analogs which were synthesized by the authors of the reference). Given this interpretation, the peptide disclosed by Lakey meets all of the requirements of the claims.

✱

The following is a quotation of 35 USC §103 which forms the basis for all obviousness rejections set forth in the Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned

at the time any inventions covered therein were made, absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

Claims 1, 7-11 are rejected under 35 U.S.C. §103 as being unpatentable over Shai (*J. Biol. Chem.* 271, 7305, 1996).

As indicated previously, Shai teaches (p. 7308, col 1, 1st paragraph) that the peptide designated " (D)P<sup>7</sup>L<sup>18</sup>L<sup>19</sup> " is antibacterial but non-hemolytic. Shai does not disclose that if one of the amino acid side chains is extended by one methylene unit, that cytolytic activity will be retained, as directed to claims 1 and 7-11.

However, a peptide biochemist of ordinary skill would have expected, *a priori*, that when a side chain of one amino acid in a peptide is extended by one methylene unit, the biological activity of that peptide will remain substantially the same [*In re Shetty* (195 USPQ 753) and *In re Hass & Susie* (60 USPQ 544)]. Thus, for example, a peptide biochemist of ordinary skill would have expected that a peptide containing alanine would exhibit substantially the same activity as an otherwise identical peptide containing ethylglycine; similarly, a peptide biochemist of ordinary skill would have expected that a peptide containing phenylalanine would exhibit substantially the same activity as an otherwise identical peptide containing phenethylglycine. In making either of these selections, the result would be a peptide that is not found in nature, and one which is not excluded by the claims.

Thus, the claims are rendered obvious.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 703-308-3213. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached at (703) 308-2923. The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

*D. Lukton 1/2/03*

*Christopher S. F. Low*

CHRISTOPHER S. F. LOW  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600